

t-Butyl Alcohol - Comments of Environmental Defense Comments

(Submitted via Internet 8/27/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for t-butanol (also known as t-butyl alcohol).

The test plan for t-butanol (TBA) was submitted by Lyondell Chemical Corporation and Huntsman Corporation. The test plan and robust summaries were clearly written and represent a good model for HPV submissions. As described more fully below, we agree with all the sponsor's conclusions regarding adequacy of data and proposals for further testing.

TBA is used primarily in the synthesis of the fuel oxygenate, methyl-t-butyl ether (MTBE). MTBE is metabolized readily in a variety of biological systems to TBA so TBA is found in the bodies of wildlife and people who are exposed to MTBE. TBA was studied by the NTP including lifetime bioassays in rats and mice and extensive 90-day studies. These are more than adequate to fulfill the requirements of the HPV program for repeat dose studies.

Two developmental toxicology studies using three different mouse strains have been published by non-industry scientists. Although these studies were not conducted under formal HPV guidelines, they were published in the peer-reviewed scientific literature and seem to be fairly well done so the results should be considered credible. Therefore, we agree with the sponsor that no additional developmental toxicology studies are needed.

No reproductive toxicology studies have been conducted on TBA although the NTP did not report any histological changes in reproductive tracts following analysis of samples from the 90-day studies. Since TBA is routinely found in human blood and urine samples, we agree with the sponsor's proposal to conduct a reproductive toxicology study on TBA.

Thank you for this opportunity to comment.

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